JUL 1 7 2001

K003966/A2

Summary of Safety and Effectiveness

MICOR, INC.
Conduction Catheter

1.0 Micor Contact

Jeremiah Costello, Ph.D.
Micor, Inc.
2855 Oxford Boulevard
Allison Park, Pennsylvania 15101
Telephone: (412)487-1113
Facsimile: (412)487-1747

2.0 Device Name

2.1 Trade Name

WundCath

2.2 Classification Name

Device Name:	Catheter, Conduction, Anesthetic
Speciality:	Anesthesiology
Product Code:	FRN
Device Class:	2
Regulation No.:	21 CFR 880.5725

3.0 Predicate Devices

3.1 Micor, Inc. Spring wound Epidural Catheter (K991879)

3.2 I-Flow Conduction Catheter (K991543)

3.3 I-Flow Conduction Catheter (K994374)

4.0 Product Description/Function

4.1 **Description** The subject device is closed-ended with lateral side ports. The catheter is radiopaque and is available in 19 and 20 gauge sizes.

4.2 **Function** The subject device has similar performance characteristics and will function the same as the predicate devices K991543 and K994374.

5.0 Comparison of the Subject Device and Predicate Devices for Equivalence

5.1 **General** Catheters manufactured from the resin material in the subject device, and being used for the delivery of anesthetic agents, have been on the U.S. market for a number of years. These include catheters fabricated and legally-marketed by Micor, Inc.

5.2 **Technological Characteristics** The technological characteristics of the subject device, as compared to those of Micor's spring wound catheter K991879, are substantially equivalent.

5.3 **Materials** The materials incorporated in the subject device are substantially equivalent to those contained in the legally-marketed predicate, K991879.

5.4 **Intended Use** The subject device is equivalent to the predicates, K991543 and K994374 in its use for continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside the epidural space. Routes of administration may be intraoperative, subcutaneous or percutaneous.

5.5 **Conclusion** No new issues of safety or effectiveness are raised by the design of this device. The Micor Conduction Catheter is equivalent to the cited predicate devices, K991543 and K 994374, in its performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

Mr. Jeremiah Costello
Micro Incorporated
2855 Oxford Boulevard
Allison Park, Pennsylvania 15101

Re: K003966
Trade/Device Name: Wundcath Conduction Catheter
Regulation Number: 880.5725
Regulatory Class: II
Product Code: FRN
Dated: April 30, 2001
Received: May 1, 2001

Dear Mr. Costello:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K003966

510(k) Number (if known)

Conduction Catheter

Device Name

(NOTE: These are appropriate indications for use for this device as established by the equivalent predicate devices.)

Indications for Use:

The Conduction catheter is intended for administration of local anesthetics or narcotics into intraoperative sites for post operative pain management and for regional anesthesia, outside of the epidural space. Routes of administration may include intraoperative, subcutaneous or percutaneous. The catheter is not intended for intravenous or intramuscular use.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____

(Per 21 CFR 801.109)

Paloma Ciccante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003966